

**Assessment of the USEPA Region 1 New England
Laboratory Certification Program for Drinking Water**

Conducted by the

**Office of Water
Office of Ground Water and Drinking Water
Technical Support Center**

Date of Evaluation: September 23-24, 2014

Date of Report: November 16, 2015



**U. S. ENVIRONMENTAL PROTECTION AGENCY
Cincinnati, Ohio 45268**

Table of Contents

	<u>Page</u>
1. Introduction.....	4
2. Regional Drinking Water Laboratory Certification Program	4
3. Regional Oversight of Primacy State Drinking Water Certification/Accreditation Programs.....	5
3.1. Review of Regional Standard Operating Procedures for Assessing Primacy State Drinking Water Certification/Accreditation Programs	5
3.2. Regional Personnel Qualifications/Responsibilities for Assessing Primacy State Drinking Water Certification/Accreditation Programs	6
3.3. Regional Procedures for Assessing Primacy State Drinking Water Certification/Accreditation Programs	6
3.4. Regional Records Management for Assessing Primacy State Drinking Water Certification/Accreditation Programs	10
4. Regional Oversight of Laboratories	10
4.1. Review of Regional Standard Operating Procedure for Auditing Principal and Non-Primacy Laboratories	10
4.1.1 Proficiency Test Tracking	11
4.2. Regional Personnel Qualifications/Responsibilities for Auditing Principal State and Non-Primacy State Laboratories.....	12
4.3. Regional Procedure for Auditing Principal State and Non-Primacy State Laboratories	13
4.4. Regional Records Management for Auditing Principal State and Non-Primacy State Laboratories	16
5. Regional Communication and Technical Assistance	16
5.1. Regional Communication	17
5.2. Regional Technical Assistance	17
6. Assessment Summary	18
6.1. Commendations	18
6.2. Recommendations/Action Items	19
6.2.1. Repeat Recommendation	19
6.2.2. New Recommendation.....	19
6.3. Findings/Corrective Actions	20
6.3.1. Repeat Finding	20
6.3.2. New Finding.....	20

7. Signatures	21
Attachment A. Agenda for September 2014 Region 1 RLCPA	22
Attachment B. Attendees at the September 2014 Region 1 RLCPA.....	23
Attachment C. Region 1 Laboratory Certification Program Organizational Chart	24

1. Introduction

The "Manual for the Certification of Laboratories Analyzing Drinking Water" (MCLADW) (Fifth Edition, 2005, EPA 815-R-05-004) requires the Office of Ground Water and Drinking Water (OGWDW) to "review the EPA Regional drinking water certification programs annually and evaluate the resources and personnel available in each Region to carry out the certification program." Paper assessments in the form of questionnaires are performed annually with on-site assessments conducted at least triennially.

EPA Region 1 New England Regional Laboratory Certification Program (RLCP) is based at 11 Technology Drive, North Chelmsford, MA 01863. EPA Region 1 oversees 6 Primacy States, their Principal State Laboratory (PSL)/PSL networks and one non-Primacy lab for the Aroostook Band of Micmacs.

Judith Brisbin and Michella Karapondo from EPA's OGWDW Technical Support Center (TSC) performed the on-site Regional Laboratory Certification Assessment (RLCPA). The RLCPA was held at EPA Region 1's Laboratory Certification Program (LCP) office in North Chelmsford on September 23 and 24, 2014. The opening conference for the RLCPA was held on September 23, 2014. The file and documentation review took place on September 23 and 24, 2014. The exit debrief took place on September 24, 2014. The agenda and list of attendees are in Attachments A and B, respectively.

2. Regional Drinking Water Laboratory Certification Program

Approximately 1.7 full-time equivalents (FTEs) are committed to the RLCP, including partial FTE allotments for the Laboratory Certification Program Manager (LCPM), four chemistry Certification Officers (COs), and one microbiology CO. The Regional Administrator, Curt Spalding, has delegated certification authority to Robert E. Maxfield, who is the Regional Laboratory Director. Ann Jefferies is the LCPM. See the organizational chart in Attachment C. The Regional Laboratory Certification Program (RLCP) staff are located in the same building as the Regional Laboratory and share a close association. Other Regional Laboratory staff include the Deputy Director, Arthur Johnson, and Chemist, Ernest Waterman. The Regional COs are listed in Table 2.1. An additional person, Dan Curran, took the chemistry course in August 2014. Another person, Jack Paar, passed the microbiology course in 1995, but has not participated in a recent audit.

Table 2.1 Area of Responsibility and Training Status of Regional Certification Officers

Regional Certification Officer	Area(s) of Responsibility	Year Passed EPA CO Training	Year Last Audited EPA CO Training
Dan Boudreau	Chemistry	2001	Never audited; past due.
Michael Dowling	Chemistry	1990	Never audited; past due.
Inna Germansderfer	Chemistry	2006	Never audited; past due.
Maureen Hilton	Microbiology	2002	Never audited; past due.
(William) Scott Clifford	Chemistry	1988	Never audited; past due.

3. Regional Oversight of Primacy State Drinking Water Certification/Accreditation Programs

The Regions oversee the LCPs in States and Tribal Nations. As stated in the MCLADW, the Regions' responsibilities include performing "an annual review of State/Tribal certification programs, Proficiency Testing (PT) results and the adequacy of State/Tribal programs for certifying laboratories." This section reviews the documents and procedures used by the Region to perform these tasks.

3.1. Review of Regional Standard Operating Procedures for Assessing Primacy State Drinking Water Certification/Accreditation Programs

The information to be reviewed during a State Laboratory Certification Program Assessment (SLCPA) is identified in detail in Region 1's Standard Operating Procedure (SOP), "Standard Operating Procedure for the Review of States' Laboratory Certification Programs." The SOP includes a checklist of questions, describes the items that should be reviewed in the files, and outlines the Region's expectations regarding issuance of the report by the State to its CO, including follow-up and corrective actions taken after the SLCPA. It has been the practice of the EPA New England program to observe a laboratory audit conducted by each State Laboratory Certification Program's (SLCP's) once every two to three years.

The document-controlled version of the Region's SLCPA SOP, Revision 2, is listed in the Region's SOP database, and is indicated as "approved" even though the signature page in the source file is blank. The cover page marks the document effective date as December 20, 2011.

EPA Region 1's SLCPA SOP contains four of the five administrative/programmatic elements listed in the 2007 EPA-QA/G-6, <http://www.epa.gov/quality/qs-docs/g6-final.pdf>, including a Title Page, Table of Contents, Procedures for the Regional oversight of Primacy SLCPs, and References. However, the SOP does not include a quality control and quality assurance section.

3.2. Regional Personnel Qualifications/Responsibilities for Assessing Primacy State Drinking Water Certification/Accreditation Programs

To date, current staffing levels appear inadequate to enable the Region to complete required assessments. The LCP has experienced diminished resources and only partial filling of the vacancies created by retirement in the recent years. Furloughs, vacation, and extensive sick leave reduced program staff productivity by about 0.25 FTE in 2013. Also, there are ongoing discussions of the appropriate location of the LCP — the lab or QA. This topic was unresolved at the time of the audit. Even more significantly, Ms. Jefferies near-term retirement is viewed by Mr. Johnson as an upcoming risk or vulnerability, and the TSC team agrees with his assessment. Mr. Johnson requested examples of best practices for succession planning in other Regions. Ms. Jefferies was trained by her predecessor, and overlapped with him for a protracted period and joined him for audits before she assumed responsibility. The TSC team is concerned that Ms. Jefferies will be unable to provide equivalent training for her successor due to the timing of the regional audits. The only upcoming audit is for the Connecticut LCP, and no audits will be conducted between the time that the successor is hired and Ms. Jefferies' retirement. Fortunately, the EPA Region 1 liaison from the drinking water program office, Ms. Kwong, is familiar with the program and will be able to provide support to her successor.

Staff may need to attend refresher CO courses to ensure that they are properly trained to conduct assessments. Sometimes it has been challenging to obtain funds to attend training.

3.3. Regional Procedures for Assessing Primacy State Drinking Water Certification/Accreditation Programs

EPA Region 1's SLCPA SOP contains a thorough description of procedures for the Regional oversight of Primacy SLCPs based on EPA's MCLADW as well as those based on The NELAC Institute (TNI) standards.

The LCPM (Arthur Clark in 2010 & 2011; Ann Jefferies in 2012, 2013 & 2014) and a representative of the EPA Region 1 Drinking Water Program (Ellie Kwong) review Primacy SLCPs based on the MCLADW.

Historically, the LCPM has participated in the evaluations of the National Environmental Laboratory Accreditation Program (NELAP) Accreditation Bodies (ABs), the New Hampshire Environmental Laboratory Accreditation Program (NH ELAP). The LCPM also reviews the Assessment Appraisal Forms submitted voluntarily by each laboratory accredited by the NH ELAP. The laboratories use these forms to rate the quality of the NH ELAP assessments.

The LCPM participated as a team member on the most recent NELAP/TNI evaluation of the NH ELAP in 2014, which also included the lab audit. Ms. Jefferies reviewed the evaluation report and provided feedback on the review of the NH ELAP including preparation of the report for the lab assessment observation.

Ms. Jefferies shadowed the NH ELAP as they assessed the Vermont PSL, which allowed her to see the Vermont PSL audit as well.

EPA Region 1 LCP oversight assessments of the SLCPs routinely include inquiries concerning the use of third party auditors/assessors and their competency, qualifications, experience, and

freedom from conflict of interest. The Region also asks about procedures for the State's oversight of third parties.

Table 3.1 provides an overview of the SLCPs under the Region's purview.

Table 3.1 Regional Oversight of Primacy State Drinking Water Laboratory Certification/Accreditation Programs

State	Agency	Assessor	Date of last SLCPA	Date of last signed report	Number of Laboratories Certified/Accredited By the State: In State (Out of State)			
					Chemistry	Micro	Rads	Crypto
CT	CT DPH ELCP	Region 1	April 2011	Not in file*	43 (70)	39 (27)	7 (17)	0 (3)
MA	Mass DEP LCP	Region 1	February 2013	Not drafted	24 (33)	54 (11)	2 (8)	0 (0)
ME	DHHS/CD C LCP	Region 1	March 2010	March 23, 2010	21 (41)	18 (15)	1 (5)	0 (0)
NH	NH ELAP	NELAP Eval. Team w/ Region 1	May 2014	July 28, 2014	15 (40)	21 (19)	4 (15)	0 (2)
RI	RI DOH LCP	Region 1	March 2013	Not drafted	9 (34)	10 (12)	0 (7)	0 (0)
VT	VT DOH DW LCP	Region 1	August 2012	Not in file*	3 (21)	7 (11)	0 (9)	0 (0)

*Hard copies of electronic files were provided.

The SOP calls for triennial SLCPAs. However, two reviews are overdue and two reports from SLCPAs performed in 2013 were never generated. These delays were due in part to the LCPM's extended medical leave in 2013. Other details are provided below.

- The SLCPA for Connecticut was due in 2014 but has been delayed until 2015. Two reasons contributed to this decision. First, the Connecticut PSL moved in 2014. The Region usually performs the SLCPA at the same time as the lab audit, so the move presented a scheduling conflict and workload constraints for the COs. Conducting the Connecticut SLCPA in 2015 is ultimately beneficial, as the audits will be spaced out more evenly in the future.
- The SLCPA for the Maine PSL was due in 2013 but has been delayed until 2015 due to turnover in the State LCP and the Region elected to delay the review until the new CO could meet and speak knowledgeably about their program. The Maine LCP had three different COs between June 2011 and 2014 including the current CO and no CO between September 2012 and February 2013.

- The SLCPA for the Massachusetts and Rhode Island programs were completed in February 2013 and March 2013. However, reports were not prepared for either state due to the extended leave of the LCPM. Comments were shared with both programs. There were no major findings identified for either program.

The LCPM's role may change in the future due to declining resources in EPA Region 1. The SOP notes that beginning in January 2012, the LCPM might not be able to participate in the NELAP on-site assessments. The EPA Regional Science and Technology (RS&T) Directors have decided to decrease EPA Region 1's involvement in the oversight of the NELAP lab accreditation programs. There is a strong push to disinvest as a way for the Region to juggle inadequate resources. The LCPM believes it is important for EPA to continue supporting the participation of the Regions in the evaluations of the NELAP ABs. At the least, Ms. Jefferies would want to attend some meetings and review the NELAP AB evaluation report.

The responsibility and training status of each CO employed by the Primacy States in EPA Region 1 are listed in Table 3.1. EPA COs, NELAC Assessors, and third-party auditors and/or any additional third-party technical expertise utilized to perform audits are included.

Table 3.2 Area of Responsibility and Training Status of Certification Officers Utilized by Primacy States

Name/Affiliation of State Utilized Certification Officer	State	Area(s) of Responsibility	Year Passed EPA CO Training	Year Last Audited EPA CO Training
Dermot Jones	CT	Chem, Micro, Radchem, Asbestos	1994 Chem; 1994 Micro;	Never audited; past due. Never audited; past due.
Philip Schlossberg	CT	Chem, Micro	1985 Chem; 1984 Micro	Never audited; past due. 2006 Micro, due
Ann Marie Allen	MA	Chem, Micro	1989, 1996 Chem; 1999 Micro	Never audited; past due. Never audited; past due.
John Bardzik	MA	Chem	1997 Inorganic Chem; 1989 Chem	Never audited; past due.
David Brierley	MA	Chem, Radchem	2006 Inorganic Chem; 1998 Organic Chem	Never audited; past due.
Jenna (Peardon) Kotuli	MA	Micro	2003 Micro	Never audited; past due.
Lisa Touet	MA	Chem, Micro	2000 Chem; 2002 Micro	Never audited; past due. Never audited; past due.

Name/Affiliation of State Utilized Certification Officer	State	Area(s) of Responsibility	Year Passed EPA CO Training	Year Last Audited EPA CO Training
Jennifer Jamison	ME	Chem, Micro, Radchem	2014 Chem (Inorganic); 2013 Micro; 2014 Crypto	N/A N/A N/A
Bill Hall	NH	Chem, Micro, Radchem, Crypto	2007 Chem; 2008 Micro; 2010 Crypto	2014 Chem Never audited; past due. 2013 Crypto
Henry Leibovitz, Ph.D.	RI	Chem, Micro	2005 Chem; 2006 Micro	Never audited; past due. Never audited; past due.
Ewa King, Ph.D.	RI	Chem, Micro	2000 Chem; 2002 Micro	Never audited; past due. Never audited; past due.
Dermot Jones 3 rd party assessor	RI	Chem, Micro	1994 Chem; 1994 Micro	
Matthew Sica 3 rd party assessor	RI	Chem, Micro	2004 Chem; 2004 Micro; 2011 Crypto	
Michael Sodano 3 rd party assessor	RI	Chem, Micro	1995 Inorg Chem; 1980 Chem; 1980 Micro	
William (George) Mills	VT	Chem, Micro	1990 Chem; No record of attending Micro	Never audited; past due. 1985 Micro

Nearly all COs are overdue for refresher training. Most States can travel out of state for training, but must have documentation, such as an agenda, far enough in advance to get approval. Sometimes RI staff use vacation time to attend meetings, such as the QA round table session, because travel restrictions do not allow them to leave the State.

EPA Region 1 States generally have decreasing budgets, which may present a potential CO shortage. Already, Connecticut did not replace one of its COs when the CO transferred to another State job. Maine has had difficulty attracting and retaining qualified COs. Two other

States are actively seeking ways to reduce costs through staff reductions. If any of the State COs were to leave their job, the affected State might not be able to hire a replacement.

3.4. Regional Records Management for Assessing Primacy State Drinking Water Certification/Accreditation Programs

The files include reports, correspondence, questionnaires completed by the SLCPs, and other checklists completed by the Regional review team. The SOP documents how these records should be maintained.

The Region meets the MCLADW requirements to maintain records for State certification program reviews in an easily accessible central location for a period of three years to include the last two on-site audits, or longer if required by specific State regulations.

Recordkeeping is organized and contain at least the past 6 years, as required. The LCPM keeps notes separately, in her files, and also collects notes from other participants in audits and assessments. Files are organized by Lab Certification, Correspondence, Lab documents, and travel information. Copies of Regional assessment and NELAP on-site assessment reports and annual questionnaires are kept in the files. Some information is received electronically.

4. Regional Oversight of Laboratories

The Region oversees the PSL, or PSL network of laboratories, in every State that holds Primacy. The laboratories may be EPA-certified or TNI-accredited. As stated in the MCLADW, “Regional certification officers are responsible for the certification of the principal State laboratory in each Primacy State, and are also responsible for certifying all Tribal Nation laboratories and laboratories in non-Primacy States.” EPA Region 1 oversees the PSL/PSL network in 6 Primacy States and one non-Primacy lab for the Aroostook Band of Micmacs. This section reviews the documents and procedures used by the Region to perform these tasks.

4.1. Review of Regional Standard Operating Procedure for Auditing Principal and Non-Primacy Laboratories

The procedure used by the Region to evaluate State PSLs in, “Standard Operating Procedure for Evaluating State Principal Laboratories Analyzing Drinking Water.” The document-controlled version of the SOP, Revision 6, is listed in the SOP database, and is indicated as “approved” even though the signature page in the source file is blank. The cover page marks the document effective date as December 20, 2011.

This SOP contains all five administrative/programmatic elements listed in EPA-QA/G-6: Title Page, Table of Contents, Procedures, QA/QC, and References. The sections are completed with great detail. The SOP also lists criteria, checklists, or other standards that are to be applied during the procedure.

The SOP outlines the preparatory, on-site, and report production procedures for the laboratory audits conducted by the Region or others acting on behalf of the Region (see Section 3.2 for more information). It describes the procedures for participation in NELAP audits. It lists checklists that must be used by the auditors during the audits and describes the master checklist which is provided to the lab prior to the audit. The Regional LCP SOPs are maintained in a formal OEME document control system database named Lab SOPs. State laboratory documents

are not included in the OEME document control system. The SOP does not describe procedures for recognizing laboratories through reciprocity, since the Region has no PSLs recognized through reciprocity.

A separate SOP, “Standard Operating Procedure for Evaluating State Principal Laboratories’ Analysis of Drinking Water Proficiency Testing Samples,” outlines the Region’s responsibilities for reviewing and tracking PT studies, as well as steps required if a PT study is failed. The document-controlled version of the SOP, Revision 2, is listed in the SOP database, and is indicated as “approved” even though the signature page in the source file is blank. The cover page marks the document effective date as December 20, 2011.

The SOP notes that the Connecticut Department of Public Health (CT DPH) laboratory is the only PSL in New England which is certified for the analysis of asbestos, and the lab has agreed to perform asbestos analyses for any of the other PSLs in New England. The Regional SOP for performing PSL audits includes a template for reviewing the State SOPs and a questionnaire that is submitted to the PSLs prior to the audit. The questionnaire serves as the basis for the final report.

The timeline for producing the report from the PSL audit is clearly presented in Section 9 of the SOP: “Within two weeks of the evaluation, each team member must provide their checklists, including a) either the chemistry & QA checklist or the Chapter V microbiology checklist (from MCLADW) and b) method-specific checklists, and any other comments and information related to the on-site.” The LCPM prepares the final report within two to four weeks after receiving team member reports.

The Region follows the criteria and procedures of the MCLADW for downgrading or revocation of certification. The Regional QA manager and CA must be briefed and agree to any changes to certification before the audit report is finalized.

It is possible that the laboratory may take sufficient and immediate corrective actions and avoid loss of certification before the audit report is finalized. Ms. Jefferies noted that most corrective actions are completed and issues are resolved. Sometimes labs note problems meeting corrective actions: for instance, Maine noted that the cost of PT studies was an issue.

If certification status is affected by failure to successfully complete the PT study, the certification is revoked and a new certificate and letter are sent to the lab. The letter clearly states that the new certificate supersedes all previous certifications.

The Region documents certification status on the certificate, which lists certification by method and by contaminant. There is a one-month overlap in January between annual expiration of the certification and renewal. Each certificate also has a seal, and signed versions of the certificates are mailed to the lab with an accompanying letter.

4.1.1 Proficiency Test Tracking

The PT SOP clearly explains that a laboratory’s certification status is determined by the results of EPA Region 1’s triennial audit of its capabilities as well as by the results of its analysis of PT samples. The SOP describes policies and practices, including tracking the PT data, and issuing new certificates and lists of certified analytes. In some cases, satisfactory PT data may be contradicted by audit findings. Therefore, the SOP notes that it is imperative that the LCPM

consider both the PT data and the audit findings when preparing new certificates and lists of analytes.

EPA Region 1 received copies of the PT data for all New England PSLs, including the Micmac Environmental Laboratory (which is no longer certified by EPA Region 1).

Region 1 manually tracks the data of labs they certify. The Region reminds the PSLs that have failed a PT to submit make-up data. The Region also sends them a reminder if the PSL is later than usual in submitting data. Whenever a PSL fails two consecutive PTs, its certification is downgraded one level – from certified to provisionally certified, or from provisionally certified to not certified. The Region does not allow the PSL to remain provisionally certified indefinitely.

For accredited PSLs, the Region relies upon the NH ELAP to monitor the lab's status and adjust the status as necessary. The Region has examined the NH ELAP's accuracy and timeliness of tracking PT data for the accredited PSLs and found it to be satisfactory.

The PT results tracking process in EPA Region 1's SOP is organized but time-consuming. After new certificates and analyte lists are issued by the Region each January, new PT folders are created. The completed status report tables for the last year and copies of the newly issued certificates, analyte lists, and cover letters are transferred to the new folders. The PT data and related correspondence are retained for at least six years before being archived. The PT providers' narrative reports are kept for one year, then recycled.

Ms. Jefferies tags any "Not Acceptable" PT results with a post-it sticker and notes the method that was problematic. She reviews all PT data for the year and issues certificates. If the lab failed two or more PT samples, their certification would be downgraded to provisional. Tracking the information is time-consuming, and can lead to errors. For instance:

- Two PT sample studies received from Massachusetts in May and July 2014 indicated that samples for trichloroethylene were "not acceptable" and the LCPM did not immediately take action. The problem was exacerbated because workload backlogs in 2013 had delayed issuance of certificates. Therefore, the LCPM issued a certificate on August 6, 2014 which said the lab was still certified for TCE after having reviewed two rounds of unacceptable PT results.
- A PT sample study from Massachusetts received in August 2013 showed "not acceptable" for total coliform using method SM9222B, but no action was taken until the end of the year.

4.2. Regional Personnel Qualifications/Responsibilities for Auditing Principal State and Non-Primacy State Laboratories

The SOP clearly defines required qualifications, roles and responsibilities of members of the audit team.

Historically, the LCPM has participated as an assessor, technical expert, or observer (at the AB's invitation) in each of EPA Region 1's accreditations of the DW PSLs. EPA Region 1 successfully convinced NELAP to allow the LCPM to join audits by noting that the Region would either have to evaluate the labs separately if the LCPM was not included on their team, or conduct a joint audit and achieve greater value with a team approach. If the LCPM could not participate, oversight would be done by reviewing reports and PT study data. Procedures are

dictated by NELAP. Through June 30, 2011, these labs were evaluated according to the 2003 NELAC Standard. As of July 2, 2011, NELAP laboratories are accredited according to Volume 1 of the 2009 TNI Standard: Management and Technical Requirements for Laboratories Performing Environmental Analysis.

Dr. James Webber, a Senior Research Scientist for the New York State Department of Health (NYS DOH)¹ is a nationally known expert in asbestos analysis. During the autumn prior to each on-site evaluation, the LCPM contacts Dr. Webber and his superiors and requests his assistance in evaluating the CT DPH Laboratory for asbestos analysis. Dr. Webber has graciously agreed to do this without cost, except for reimbursement for his travel expenses. As is the case for radiochemistry evaluations, it is important for the LCPM to accompany Dr. Webber during the asbestos evaluation.

The following PSLs are NELAP-accredited:

- New Hampshire Department of Health and Human Services Lab (Concord)
- Vermont Department of Health Lab (Burlington)
- The Health & Environmental Testing Lab, which is the Maine State PSL, reverted from NELAP accreditation to EPA certification in 2010. It was audited by the TSC contractor for radiochemistry in October 2010 and March 2014, and by the Region for chemistry and microbiology in March 2011, September 2011 and March 2014.

4.3. Regional Procedure for Auditing Principal State and Non-Primacy State Laboratories

The dates of the most recent audits by Region 1 of the PSLs within the Region are listed in Table 4.1. Each State in EPA Region 1 has one PSL. Most Region-certified labs are certified or have provisions to send samples to an alternate laboratory certified by the Region, as was described earlier for asbestos samples that are sent to the Connecticut PSL (CT DPH). Two exceptions are described below:

- The Micmac Environmental Laboratory in Presque Isle, Maine, is the only tribal laboratory in New England which has been certified by EPA Region 1. The Region first certified the lab in 2006, after EPA Region 1 attended the certification review of its secondary certification from the Maine Department of Health and Human Services LCP. However, it is no longer certified for any analyte. In late 2011 or early 2012, the tribe withdrew their certification for chemistry, after losing the person who conducted the chemistry analyses. The tribe hired someone who attended training in EPA Region 1, but the lab has not requested recertification. The tribe subcontracted some samples and encountered issues with holding times. (The chemistry lab may be an accredited commercial lab, reviewed by Maine, but the Region isn't certain.) After the microbiology audit later in 2012, EPA Region 1 told the lab that they would have to be decertified, due to missing documentation and other concerns. The Region debated whether to issue provisional certification, but instead said that the lab must provide corrective actions and then EPA Region 1 would come back to recertify. The tribe never provided the corrective

actions, and the lab is no longer certified by the Region. The lab voluntarily withdrew its microbiology certification. (Maine may have certified the microbiology lab, but the LCPM is unsure if it was a tribal lab or a commercial lab.)

- The CT DPH laboratory continues to be provisionally certified for two radiochemistry analytes, Radium-228 and Strontium-90, pending satisfactory implementation of corrective actions from the radiochemistry audit conducted August 2012. The laboratory is not certified for Strontium-89, based on findings from the audit and because no PT study was reported for 2013. The lab has completed the MDL studies for the two compounds. The Region received summaries of the data and forwarded the information to the TSC contractor for review.

Two laboratories, previously provisionally certified, changed status to fully certified during this triennial period:

- The CT DPH laboratory was provisionally certified in January 2014 for two of the 504.1 analytes by Method 524.3 based on their request and submission of satisfactory PT study results and required data and supporting information. The CT DPH Laboratory currently is fully certified for these analytes following completion of a second successful PT study in March 2014.
- The MA DEP laboratory was provisionally certified in 2013 for organic pesticide analytes which they previously analyzed by Methods 507 and 508, and now by Method 525.2. The lab obtained full certification for these organic pesticide analytes later in 2013 when a second PT study was successfully completed.

Table 4.1 Regional Oversight of Principal State Laboratories in Primacy States and Laboratories in Non-Primacy States – Laboratory, Location, Certification/Accreditation Entity & Date of Last On-site Audit

State/ Territory Tribe/ Other	Laboratory Name (Location)	Lab Type	Certification/Accreditation Entity Date of Last On-site Audit			
			Chemistry	Microbiology	Radiochemistry	<i>Crypto</i>
CT	Dr. Katherine A. Kelley State Public Health Laboratory (Rocky Hill, CT)	State	EPA R1 April 2011	EPA R1 April 2011	EPA R1 / TSC contractor August 2012	-----
ME	Department of Health & Human Services Health & Environmental Testing Laboratory (Augusta, ME)	State	EPA R1 March 2014	EPA R1 March 2014	EPA R1 / TSC contractor March 2014	-----
MA	Senator William X. Wall Experiment Station Department of Environmental Protection (Lawrence, MA)	State	EPA R1 February 2013	EPA R1 February 2013	Not certified ¹	-----
NH	Department of Health and Human Services Division of Public Health Services Public Health Laboratories (Concord, NH)	State	NELAP (NH ELAP) November 2013	NELAP (NH ELAP) November 2013	NELAP (NH ELAP) November 2013 (/EPA R1/ TSC contractor November 2011)	-----
RI	Rhode Island State Health Laboratories (Providence, RI)	State	EPA R1 March 2013	EPA R1 March 2013	Not certified: Samples are sent to CT DPH	-----
VT	Department of Health Laboratory (Burlington, VT)	State	NELAP (NH ELAP) August 2012 ²	NELAP (NH ELAP) August 2012 ²	NELAP (NH ELAP) August 2012 ² NH ELAP/ EPA R1/ TSC contractor Nov 2010 ²	-----
Aroostook Band of Micmacs	Micmac Environmental Laboratory (Presque Isle, ME)	State	EPA R1/ME DHHS June 2009 ³ lab withdrew certification in December 2011	EPA R1/ ME DHHS July 2012 ³ lab withdrew certification in September 2012	-----	-----

¹ MA DPH Environmental Radiation Laboratory (ERL): DPH ERL is the designated radiochemistry PSL for Massachusetts. It was last evaluated in 2006 and surrendered its certificate in 2007. In August 2010 MA DPH ERL announced its intention to become recertified in 2011.

² Vermont Dept. of Health Laboratory assessments by the NH ELAP for chemistry & microbiology and by the NH ELAP/TSC contractor for radiochemistry are scheduled for July 2014.

³ Region 1 and the Maine DHHS jointly audited the Micmac Environmental Laboratory in 2009 and 2012.

In the past, several of the PSLs have been provisionally certified for specific analytes for reasons including PT failures, not adhering to approved methods, and quality system issues in a particular analytical area. The Region's SOP states that if a lab fails two PT studies, it must be downgraded to provisional certification and complete a third PT. If the lab does not pass the third

PT study, then it will be downgraded to “not certified”. If a lab fails two PT studies, does not do a make-up study, and fails a third study, the lab also will be downgraded to “not certified”. Decisions to reinstate “provisional certification” or “certification” during the following calendar year will be made on a case-by-case basis.

Each State drinking water program in New England relies to varying extents on the commercial labs which its certification/accreditation program has certified/accredited for the analysis of drinking water compliance samples. The Region’s PSLs do not have the capacity to analyze all such samples. In fact, Massachusetts requires that all its drinking water compliance samples be analyzed by certified/accredited commercial labs.

Each State Drinking Water Program has determined that there are certified/accredited commercial labs within its own State or in other States with the capability to analyze compliance samples for all regulated contaminants. The arrangements are described below.

- The CT DPH laboratory is the only PSL in New England that is certified for the analysis of asbestos in drinking water. It has a long-standing informal agreement with the other New England PSLs that the lab will accept asbestos samples from other labs. Some of the States take advantage of this offer; some do not.
- Massachusetts has a contract with the CT DPH laboratory for the analysis of any radiochemistry samples resulting from emergencies and other non-routine occurrences.
- Rhode Island has an informal agreement with the CT DPH laboratory for the analysis of its drinking water radiochemistry samples.

4.4. Regional Records Management for Auditing Principal State and Non-Primacy State Laboratories

The MCLADW stipulates that records for on-site laboratory assessments of PSLs and Non-primacy State Laboratories should be maintained in an easily accessible central location for a period of three years to include the last two on-site audits, or longer if required by specific State regulations, and the Region’s SOP mirrors this requirement. The Region’s SOP specifies the materials that each audit team member must complete, which materials must be provided in electronic format, and the schedule to submit to the LCPM. The SOP also specifies who receives the lab audit report.

The LCPM keeps notes separately, in her files, and also collects notes from other participants in audits and assessments. Files are organized by Lab Certification, Correspondence including emails, Lab documents including PT results, and travel information. Some information is received electronically. All records are retained for at least 6 years.

5. Regional Communication and Technical Assistance

The Region’s oversight of the SLCPs includes providing technical assistance to the States. As stated in the MCLADW, the Region’s responsibilities include “(sponsoring) annual meetings for the State COs and (providing) technical assistance to the States’ EPA-certified drinking water laboratories, as needed.”

5.1. Regional Communication

Ms. Jefferies and a member of EPA Region 1's Drinking Water Program staff, Ms. Kwong, are in close communication. The files contain copies of correspondence between them. Ms. Kwong also participates in the PSL audits and SLCP reviews.

Ms. Jefferies keeps annual correspondence files for her States. The files often contain emails with questions. When necessary, she forwards questions from the States to Ellie Kwong or to TSC for additional input.

The New England Certification Officers (NECO) meet as a semi-informal organization of all State and Regional environmental certification and accreditation officers in New England. NECO was organized about 25 years ago to provide a forum to address common concerns related to the certification of environmental laboratories and to develop common approaches to laboratory certification. NECO does not have by-laws. Chairmanship is rotated among the State certification/accreditation program managers; each chairmanship continues until the current chair asks to be replaced.

NECO plans in-person meetings annually. The 2014 annual meeting was held May 2014 in Concord, NH. An agenda is produced for each meeting, particularly if the meetings are in person, so that State staff can obtain travel approval. NECO conducts quarterly meetings by conference call during the quarters when the annual meeting does not occur. The first quarter call occurred in February and the third quarter call was replaced by the meeting of States on-site during the RLCPA.

The Region provided PSL Auditor Training in March 2014, which was attended by three of the five EPA Region 1 COs, including Dan Boudreau, Maureen Hilton, and Scott Clifford, and the Region 1 Drinking Water Program liaison, Ellie Kwong. The training focused on key points and information to search for during an audit, discussed what happened in the past, and described what would be relevant or should be reviewed in the future. These refresher training sessions would be done each year of audits. For instance, before the Micmac Environmental Lab review, the Region had a call with the Maine CO.

5.2. Regional Technical Assistance

TSC provided a Drinking Water Update presentation for Regional and State COs during the September 2014 on-site visit to EPA Region 1, which was attended by all six states in the Region. Four states attended in person and two states attended by conference call. In all, 12 state COs and 1 state administrative contact attended the presentation.

The LCPM and State COs are in frequent contact with each other, seeking advice and assistance from each other freely. Through NECO, the group has jointly developed and issued guidance such as a compilation of approved sample collection methods for drinking water analyses and quality assurance project plans. Evidence of this communication is in the correspondence files. Each State in the Region has a correspondence file for each year.

Correspondence over the last year included discussions/clarifications regarding:

- MA DEP: data reporting requirements, reduced monitoring criteria, where to find approved methods, and the voluntary recall of Colitag Media.

- CT DEP: incubation times, holding times, PT requirements for vinyl chloride, updates on laboratory personnel, the helium shortage, the use Colisure in a Quant-Tray for qualitative testing, and surrogates.
- ME DHHS: method contacts, an offer to allow a State CO to shadow a Regional CO, and discussion about who would take the CO training offered by Cincinnati. The EPA Region 1 LCPM has conducted oversight of the Maine LCP by performing a joint audit of the Aroostook Band of Micmacs tribal laboratory with the former CO, and by assisting the current CO with problems and questions, in addition to reviewing an audit report for a multi-parameter laboratory.
- NH ELAP: NH ELAP assessment appraisal, desorb time for EPA Method 524.2, preservation for EPA Method 515.4, scheduling assessments, *Cryptosporidium* laboratories approved under the Long Term 2 Enhanced Surface Water Treatment Rule, and the voluntary recall of Colitag Media.
- NH DHHS: desorb time for EPA Method 524.2.
- RI DOH: problems with Pall filters (used for membrane filtration) and an upcoming NECO meeting.
- VT DOH: scheduling assessments, an updated list of approved *Cryptosporidium* certification officers, and the voluntary recall of Colitag Media.

6. Assessment Summary

The EPA Region 1 LCPM spends about 60 percent of her time on the LCP and noted that it would be helpful to have help, such as a dedicated staff member who would understand the program, serve as a back-up in her absence, and be trained as her successor. The LCPM would have more time for her duties if she could delegate administrative efforts to issue certificates and reports, or obtain information technology assistance in developing a database for tracking proficiency test (PT) results. However, the Region does not foresee additional resources for the LCP in the near future. Mr. Maxfield explained that the next hire will be made to backfill Gerry's position as QA Manager, followed by the addition of an entry-level FTE in the QA program. The Region has allocations for FTE positions, but no resources to fill them.

6.1. Commendations

- Great file management: files were organized and subdivided to make access easier.
- Annual lab certification certificates are sent with a letter each year and include clear effective dates. If there is a change in certification status, the Region reissues the certificate with a clear explanation that this certificate supersedes all previous certifications.
- Pre-audit meetings before PSL audits with COs and States ensures team cohesiveness and answers any questions.

- SOPs were strong. Ms. Jefferies and Ms. Kwong both support continued evaluation of the NELAP program, in addition to the certification responsibilities in non-NELAP states. Close oversight of the AB is an advantage, as consistency between the EPA and TNI programs is preserved with the LCPM's participation and any concerns are noted by the program side too.

6.2. Recommendations/Action Items

The following items are suggested action items aimed at strengthening the RLCP. These items are not deficiencies and do not require corrective actions; they are simply suggestions.

6.2.1. Repeat Recommendation

- There are no repeat recommendations.

6.2.2. New Recommendation

- The LCPM should not delay until the end of the year to issue a downgraded certificate after two failed PT sample results. Action on these results should be sooner.
- The anticipated retirement of the LCPM represents a vulnerability, and the team recommends that a succession plan should be determined which allows overlap between the new LCPM and Ms. Jefferies. The team noted that Ms. Jefferies will perform the last lab audit that will be due before her retirement well in advance of a new hire, which is unfortunate as she will be unable to train the hire in person. Once a new entry-level person is hired, the Director may be willing to have them shadow TSC when they do an audit of another RLCP. TSC plans to conduct audits in EPA Region 4 and EPA Region 6 in 2015.
- The Region may want to explore adding staff to help with the LCPM's workload on tasks outside the LCP. Reallocation of some of the non-drinking water duties assigned to the LCPM would allow more resources for overseeing the SLCPs.
- Regions may include multiple copies of documents in the files, but it is helpful to clarify whether a document is the original. The team recommends that a "Copy" stamp be used to make this distinction.
- TSC recommends refresher training for COs, as most staff have not attended the course in the past 5 to 8 years. The Director offered to host training in EPA Region 1 and believes it also would be good for the Regional lab staff. (Dr. Brisbin noted that TSC needs 8 lab analysts for 9 hours for the chemistry course, plus additional help for presentations.) The next opportunity to host training would be in 2017, as the course rotates from East to West coast and training has already been scheduled for 2015 in the East. The Director noted that their room could host between 50-60 students. Training usually occurs in September, but Mr. Maxfield prefers May or October as September is the end of the federal fiscal year and June is the beginning of the field season, when the lab is busier, however either June or September are workable.

- Since the NH ELAP certifies programs in both New Hampshire and Vermont, TSC recommends that EPA Region 1 issue a separate certification letter to confirm their support for the delegated program. There are sensitivities in the delegation of responsibility from the Region to the State, particularly in the instance where the NH ELAP audits its own State lab, and the certification letter clarifies the delegation authority.

6.3. Findings/Corrective Actions

The following items are considered deficiencies in the Region 1 program and require corrective action; corrective actions must be submitted to OGWDW and documented upon completion.


6.3.1. Repeat Finding

- There are no repeat findings.

6.3.2. New Finding


- The Massachusetts and Rhode Island reports for their assessments in February 2013 and March 2013, respectively, need to be prepared. Comments have been shared with the states and no major findings were identified.
- The Connecticut lab audit is overdue and should be conducted in 2015.

7. Signatures



OGWDW, TSC Lead Assessor
TSC Laboratory Certification Team Leader
Judith A. Brisbin, Ph.D.

11-16-2015
Date



OGWDW, TSC Assessor
Michella Karapondo

11-17-2015
Date

Attachment A. Agenda for September 2014 Region 1 RLCPA

Regional Review – Region 1 Lab Cert Program			
Tuesday September 23, 2014		Location	Invitees
9:00 AM – 9:30 AM	Opening Conference at Region 1 Program Office		Ann Jefferies, Judy Brisbin, Michella Karapondo, Ellie Kwong, Robert Maxfield, Arthur Johnson, Ernie Waterman, Cadmus (Laurie Potter & K. Erina Keefe)
9:30 AM – 12:00 PM	Region 1 file review		Judy, Michella & Cadmus
12:00 PM – 1:00 PM	Lunch		
1:00 PM – 5:00 PM	Continue Region 1 file review		Judy, Michella & Cadmus
Wednesday September 24, 2014			
9:00 AM – 9:45 AM	Continue Region 1 file review		Judy, Michella & Cadmus
9:45 AM – 10:00 AM	Prepare for presentation (audio/video check, phone line, etc.)	Kennebec Conference Room	Ann, Judy, Michella & Cadmus
10:00 AM – 12:00 PM	Drinking Water Update Presentation	Kennebec Conference Room	Ann, Judy, Michella, State COs, Regional COs, managers, and staff
12:00 PM – 1:00 PM	Lunch		
1:00 PM – 2:30 PM	Continue Region 1 file review		Judy, Michella & Cadmus
2:30 PM – 3:30 PM	Closing Meeting		Ann, Judy, Michella, Robert, Arthur, Ernie, Cadmus(Laurie & Erina)
3:30 PM – 5:00 PM, if needed	Complete Region 1 file review		Judy, Michella & Cadmus

Attachment B. Attendees at the September 2014 Region 1 RLCPA

	Participant	Program	Role	Meeting(s)
1.	Ann Jefferies	U.S. EPA Region 1	RLCPM	All
2.	Ellie Kwong	U.S. EPA Region 1	Liaison, Drinking Water Program	All
3.	Arthur Johnson	U.S. EPA Region 1	OEME Deputy Director, QA Manager	All
4.	Robert Maxfield	U.S. EPA Region 1	OEME Director	Entrance, Exit
5.	Ernie Waterman	U.S. EPA Region 1	Branch Chief, EIA, OEME	Entrance, Exit debrief
6.	Dermot Jones	CT	CT DPH	TSC presentation
7.	Philip Schlossberg	CT	CT DPH	TSC presentation
8.	Ann Marie Allen	MA	MA DEP	TSC presentation
9.	John Bardzik	MA	MA DEP	TSC presentation
10.	David Brierley	MA	MA DEP	TSC presentation
11.	Jenna (Peardon) Kotuli	MA	MA DEP	TSC presentation
12.	Lisa Touet	MA	MA DEP	TSC presentation
13.	Christine Blais	ME	ME DHHS	TSC presentation
14.	Jennifer Jamison	ME	ME DHHS	TSC presentation
15.	Bill Hall	NH	NH DES	TSC presentation
16.	Donna Jones	NH	NH DES	TSC presentation
17.	Henry Leibovitz, Ph.D.	RI	RI DOH	TSC presentation
18.	William George Mills	VT	VT DOH	TSC presentation
19.	Katrina Kipp	U.S. EPA Region 1	Branch Chief, ECA, OEME	TSC presentation
20.	Dave McDonald	U.S. EPA Region 1	NERL, ECA	TSC presentation
21.	Judith Brisbin	U.S. EPA OGWDW/TSC	TSC Lead Assessor	All
22.	Michella Karapondo	U.S. EPA OGWDW/TSC	TSC Lead Assessor	All
23.	Laurie Potter	Cadmus	TSC Contractor	Entrance, Exit
24.	K. Erina Keefe	Cadmus	TSC Contractor	Entrance, Exit

Attachment C. Region 1 Laboratory Certification Program Organizational Chart

